IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff*, v. ANTHONY G. BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MARYLAND, and KRISTOPHER RUSINKO, in his official capacity as BOARD PRESIDENT OF THE MARYLAND BOARD OF PHARMACY, *Defendants*.	Civil Action No. 1:24-cv-01557

MEMORANDUM IN SUPPORT OF
NOVARTIS'S MOTION FOR PRELIMINARY INJUNCTION

Catherine E. Stetson*
Susan M. Cook (D. Md. Bar No. 21636)
Karl A. Racine**
Marlan Golden*
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, DC 20004
Tel: (202) 637-5600
cate.stetson@hoganlovells.com
susan.cook@hoganlovells.com

**Pro Hac Vice Motion Forthcoming*
***Application for Admission Forthcoming*

Attorneys for Novartis Pharmaceuticals Corporation

Dated: May 29, 2024

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Pages

CASES

TABLE OF AUTHORITIES–CONTINUED

Pages

TABLE OF AUTHORITIES–CONTINUED

Pages

TABLE OF AUTHORITIES–CONTINUED

Pages

TABLE OF AUTHORITIES–CONTINUED

Pages

STATUTES

TABLE OF AUTHORITIES–CONTINUED

Pages

REGULATIONS

TABLE OF AUTHORITIES–CONTINUED

Pages

OTHER AUTHORITIES

INTRODUCTION

The Supreme Court has held that state laws cannot be used to enforce the federal 340B statute, which requires drug manufacturers to provide deeply discounted prices on their covered outpatient drugs to qualifying "covered entities"—hospitals and clinics meeting specified statutory criteria. 42 U.S.C. § 256b. That decision makes sense: The federal 340B Program is a unified federal regulatory scheme, carefully constructed by Congress, and governed by a comprehensive framework of federal statutes and regulations that collectively define the obligations imposed on regulated participants. Allowing states to tinker with the federal framework would undermine Congressional objectives. Nonetheless, the State of Maryland has recently enacted a law (H.B. 1056) that purports not only to enforce the federal law but also to substantially expand the obligations imposed on drug manufacturers under the federal statute. *See* 2024 Md. Laws ch. 962 (H.B. 1056 & S.B. 986 (2024)).[1] Maryland's law is unconstitutional, for multiple reasons.

First, H.B. 1056 directly conflicts with Congress's carefully designed federal program. The Maryland law requires manufacturers to provide the federal 340B discount on an unlimited number of transactions involving for-profit pharmacies (known as "contract pharmacies"). But in implementing the federal 340B Program, Congress detailed 15 specific types of "covered entities" that qualify for discounts on manufacturers' outpatient drugs. For-profit pharmacy chains are not on that list. For that reason, four federal courts (including the D.C. Circuit and the Third Circuit) have held that federal 340B law does *not* require manufacturers to recognize an unlimited number of contract pharmacies, noting that this omission was a deliberate choice Congress made. Yet that is precisely what Maryland's H.B. 1056 purports to mandate, greatly expanding the scope of the federal discounting obligation in conflict with federal law.

[1] *Available at* https://mgaleg.maryland.gov/2024RS/bills/hb/hb1056T.pdf.

H.B. 1056 further conflicts with the federal 340B enforcement process by purporting to create its own state-level 340B enforcement mechanism. Congress created two exclusive pathways to resolve disputes arising under the 340B statute: (i) direct enforcement by federal agencies, with the possibility of a civil monetary penalty in the case of a knowing and intentional overcharge, and (ii) an Administrative Dispute Resolution process that serves as the exclusive means for regulated entities to bring narrow categories of private claims relating to the federal 340B law. Congress gave no authority to the States to administer, interpret, or enforce any aspect of the 340B Program. Yet H.B. 1056 purports to do exactly that.

The Maryland law also is preempted by federal laws governing drug regulatory exclusivity periods and patent protection—including the Food, Drug, and Cosmetic Act (FDCA), as amended by the federal Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act), and federal patent laws. In these interwoven statutes, Congress spelled out a grand bargain: Brand name manufacturers are driven to research, develop, and bring to market pharmaceutical products on the promise that they will obtain federally protected, exclusive rights to sell their products at market prices for a specified period of time. These exclusivity periods include both patent periods and regulatory exclusivity periods tied to certain aspects of a particular drug's approval by FDA. Once those regulatory exclusivity and patent periods expire, generic manufacturers are permitted to utilize the drug development work done by innovator manufacturers to obtain streamlined approval of generic products. H.B. 1056 undermines the incentives of federal law by requiring Novartis to make its drugs available at heavily discounted prices in a broader set of transactions *before* those federally protected periods have run, undermining the bargain carefully constructed by federal law. That frustrates the purposes of Congress.

Finally, Maryland's H.B. 1056 violates the dormant Commerce Clause by fueling an economically protectionist regime. First, the state law unlawfully regulates wholly out-of-state transactions between manufacturers and wholesalers, and it does so with both discriminatory intent and discriminatory effect. It also privileges in-state pharmacies' economic interests at the expense of out-of-state manufacturers**.**

Absent immediate judicial intervention enjoining H.B. 1056, Novartis will suffer irreparable harm. Once the law becomes effective on **July 1, 2024**, Novartis will risk violating Maryland law merely by continuing to implement a contract pharmacy policy that has already been expressly declared lawful by other federal courts applying the federal 340B law. The company also faces the imminent threat of unconstitutional state administrative proceedings and draconian civil and criminal penalties—none of which are permitted under federal law. And because neither federal law nor state law provides any obvious mechanism for Novartis to recover the state-mandated discounts once given, even if this Court were ultimately to conclude that H.B. 1056 is unconstitutional, all of the losses from the unlawfully mandated discounts Novartis would have paid in the meantime—amounting potentially to millions of dollars—would be irrecoverable.

If H.B. 1056 is not enjoined, Novartis will continue to suffer severe irreparable harm and loss of its constitutional rights on an ongoing basis. Novartis therefore requests a preliminary injunction enjoining enforcement of H.B. 1056 pending a decision on the merits.

STATEMENT OF FACTS

A. Statutory and Regulatory Background

The 340B Program

In 1992, Congress created the 340B Drug Pricing Program, which requires participating pharmaceutical manufacturers to provide deep discounts on their covered outpatient drugs to

qualifying hospitals and clinics. 42 U.S.C. § 256b(a). Qualifying hospitals and clinics are known as "covered entities," defined by statute to refer to specified types of non-profit hospitals and federal grantees serving poor, uninsured, underinsured, or otherwise vulnerable patient groups. *Id.* A stated purpose of the program was to provide "protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384 (II), at 12 (1992). As a condition of federal payment being available under Medicaid and Medicare Part B for its covered outpatient drugs, a manufacturer must agree to participate in the 340B Program. 42 U.S.C. § 1396r-8(a)(1).

At its core, the 340B Program requires a participating pharmaceutical manufacturer to charge a covered entity no more than the 340B ceiling price—a discounted price calculated under a prescribed statutory formula—for each unit of a covered outpatient drug purchased by that covered entity. *Id.* §§ 256b(a)(1), (a)(4), (b)(1). A participating manufacturer "shall . . . offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* § 256b(a)(1).

The statute defines the term "covered entity" narrowly, to ensure that the 340B Program's steep discounts benefit only select safety-net providers. *Id.* § 256b(a)(4). To count as a "covered entity," a provider must qualify as one of the 15 types specifically enumerated by statute. These include certain entities operating under a federal grant as well as particular types of non-profit hospitals, such as certain children's hospitals and freestanding cancer hospitals. *Id.* The 340B Pharmaceutical Pricing Agreement (PPA), which a manufacturer must execute to participate in the 340B Program, states that the term "covered entities" means "certain Public Health Service

grantees, 'look-alike' Federal Qualified Health Centers, and disproportionate share hospitals." PPA § 1(e)(1).[2]

The 340B statute contains two important limitations to protect against abuse. First, it prohibits "duplicate discounts"—a manufacturer cannot be required to both pay a Medicaid rebate and provide a 340B discount on the same unit of drug. To accomplish this, a covered entity is prohibited from requesting payment under Medicaid for a unit of a covered outpatient drug purchased under the 340B Program. 42 U.S.C. § 256b(a)(5)(A)(i). Second, to prevent diversion, the statute prohibits a covered entity from reselling or otherwise transferring a 340B drug to "a person who is not a patient of the entity." *Id*. § 256b(a)(5)(B).

The 340B statute lays out two exclusive enforcement remedies. First, the Department of Health and Human Services (HHS) is given direct enforcement powers, including the ability to seek civil monetary penalties (CMPs). *Id.* § 256b(d)(1)(B)(vi). And second, the statute requires the Secretary of HHS to promulgate regulations establishing an Administrative Dispute Resolution (ADR) process allowing covered entities and manufacturers to resolve specific narrow categories of disputes arising under the 340B Program. *Id*. § 256b(d)(3). The statute describes two narrow claim categories that are funneled to administrative dispute resolution: (1) "claims by covered entities that they have been overcharged for drugs purchased under this section," and (2) claims by manufacturers relating to duplicate discounts and drug diversion. 42 U.S.C. § 256b(d)(3)(A).

The Health Resources and Services Administration (HRSA), the subagency responsible for administering the 340B Program, recently finalized a regulation reflecting the most recent iteration of that ADR pathway. In that regulation, HRSA has recently taken the position—rightly or wrongly—that the ADR pathway is available to covered entities claiming that they were

[2] *Available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/manufacturer-ppa-addendum.pdf.

overcharged by a manufacturer for a covered outpatient drug, "including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 89 Fed. Reg. 28,643, 28,657 (Apr. 19, 2024).

Contract Pharmacy Arrangements

In the early years of the 340B Program, covered entities dispensed 340B-purchased drugs through their own in-house pharmacies. Verified Compl. ¶ 19. But over time, covered entities began entering into contractual arrangements with third-party pharmacies (so-called "contract pharmacies") for the purpose of dispensing 340B-purchased drugs. *Id.* Under these arrangements, instead of drugs being shipped to the covered entity for dispensing by its in-house pharmacy, drugs are shipped to the contract pharmacy—often a large, national chain—for dispensing there. *Id.*

Contract pharmacy arrangements, including those in Maryland, traditionally involve a "virtual inventory" or "replenishment" model. *Id.* ¶ 20. Under this model, the contract pharmacy starts with an inventory of commercially purchased product and dispenses all units of the drug from this common inventory, regardless of whether the individual to whom a unit is dispensed is a patient of the covered entity. *Id.* That is because the contract pharmacy itself typically has not determined at the time of dispensing whether the individual receiving the prescription is a "patient" of the covered entity. *Id.*; *see also Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir. May 21, 2024) ("Slip Op.") at 8. That determination is made afterward. Verified Compl. ¶ 20. Where it is believed that the individual is a covered-entity patient (based on an opaque formula generally not shared with manufacturers), the covered entity purchases a "replenishment" unit at the 340B price and directs shipment to the contract pharmacy—which commingles the 340B-purchased unit with commercially purchased units in its common inventory. *Id*; *Novartis*, Slip Op. at 8. The kicker: the 340B replenishment unit is treated as it if had been purchased at the

commercial price—and thus is available for dispensing to anyone, including a non-patient of the covered entity—even though it has in fact been purchased at the 340B price. *See* HHS Off. of Inspector General (OIG), *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 5 (Feb. 4, 2014), *available at* https://oig.hhs.gov/oei/reports/oei05-13-00431.pdf.

It is the covered entities and contract pharmacies—most of which are major for-profit pharmacy chains—that benefit from this explosion in discounts, not necessarily patients. *See Novartis*, Slip Op. at 8–9 ("The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount."); *see also* Government Accountability Off., *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs* Improvement, at 35, 43–44 (June 2018) (nearly half of covered entities reported they never provide any discount to patients who use their contract pharmacies, with many of the other half reporting that discounts are rarely given to patients).[3] In fact, it is often not determined until after the point of sale whether the covered entity will seek a 340B discount on the transaction. *Novartis*, Slip Op. at 8 ("Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount.").

HRSA's Evolving Position on Contract Pharmacies

In 1996, HRSA issued guidance announcing that the agency would not preclude covered entities lacking an in-house pharmacy from entering into a contractual relationship with a single

[3] Available at https://www.gao.gov/assets/d18480.pdf.

outside pharmacy to dispense covered outpatient drugs to the covered entity's patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996).

In 2010, HRSA issued expanded guidance stating that all covered entities must be permitted to "use" an untold number of "multiple pharmacy arrangements"—with no limits on physical location, even if the covered entity has an in-house pharmacy—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). HRSA's 2010 Guidance thus purported to authorize covered entities to enter into a limitless number of contract pharmacy arrangements with any pharmacy located anywhere in the United States.

That agency policy had striking consequences. In the years following 2010, there has been an exponential increase in the number of contract pharmacy arrangements. There are now more than 33,000 pharmacy locations that act as contract pharmacies under the 340B Program. Adam J. Fein, *For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, Drug Channels (July 11, 2023).[4] This figure represents roughly half of all pharmacy locations in the U.S., and it is dominated by five major, for-profit pharmacy chains, which collectively account for 75% of all 340B contract pharmacy relationships. *Id.* Over time, 340B expenditures have swelled as contract pharmacy arrangements proliferated. In 2022, discounted purchases under the 340B Program hit a record high of $53.7 billion—a more than 22% year-over-year increase. Adam J. Fein, *The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023).[5]

[4] *Available at* https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html.
[5] *Available at* https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html#:~:text=For%202022%2C%20discounted%20purchases%20under,%2452.3%20billion%20(%2B%242.6%20billion).

This explosive growth of contract pharmacy arrangements has greatly exacerbated longstanding systemic 340B Program integrity concerns, including the risk that 340B drugs are being diverted to non-patients and/or the subject of duplicate discounts. *See, e.g.*, HHS Off. of Inspector General (OIG), *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 5 (Feb. 4, 2014), *available at* https://oig.hhs.gov/oei/reports/oei05-13-00431.pdf; Government Accountability Off., *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 36 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf.

Drug distribution channels are notoriously complex, even before contract pharmacies enter the picture. Verified Compl. ¶ 29. Most drug manufacturers, including Novartis, sell their drug products to national wholesalers and distributors like Cencora, McKesson, and Cardinal Health. *Id.* Both parties to those transactions typically are located outside of the state of Maryland. *Id.* Wholesalers and distributors in turn sell the drug products to pharmacies, often at the national level to large pharmacy chains. *Id.* These transactions also typically take place outside of the state of Maryland. Pharmacies then dispense the drugs to patients, including those located in Maryland.

When a hospital claims a 340B discount on a drug that was dispensed by a contract pharmacy, the 340B discount typically does not go directly from the manufacturer to the covered entity. Verified Compl. ¶ 30. The pharmacy typically supplies its claims data to third-party data amalgamators, which attempt to match the pharmacy's transactions against hospitals' medical claims data to identify hospital patients who visited the pharmacy. The covered entity then submits a chargeback to the wholesaler, which credits the covered entity for the 340B discount. The wholesaler then submits its own chargeback to the manufacturer to account for the difference in price. *Id.*

B. Novartis's Contract Pharmacy Policy and Resulting Litigation

Concerned about ever-increasing abuse through fast-multiplying contract-pharmacy arrangements, in late 2020 Novartis announced a new policy toward contract pharmacies. *Id.* ¶ 31. Beginning in November 2020, Novartis explained, it would recognize all contract pharmacies within 40 miles of a covered entity—an area of more than 5,000 square miles—and allow covered entities to seek exemptions based on individual circumstances. *Id.* Novartis's 40-mile limitation did not apply to federal grantees.

In December 2020, HHS opined in an Advisory Opinion (since withdrawn) that the 340B statute requires manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. *See* Advisory Opinion at 1, *available at* 340B-AO-FINAL-12-30-2020_0.pdf (hhs.gov). A few months later, pressing the same theory, HRSA issued a violation letter to Novartis, contending that Novartis's policy violated the statute and demanding immediate compliance with HRSA's view that, at the unilateral direction of a covered entity, a manufacturer is obligated to deliver 340B drugs to any contract pharmacy, on pain of an enforcement action. (HRSA's violation letter to Novartis is a public document, *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-novartis-pharmaceuticals-covered-entities.pdf). Like the Advisory Opinion, HRSA's violation letter maintained that the "Shall Offer" language of Section 340B(a)(1) imposes a "requirement" that is "not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs," meaning—in HRSA's view—that manufacturers have no "right to place conditions" on the distribution of 340B drugs. *Id.* at 1. The letter threatened enforcement actions in the form of "repayment" and civil monetary penalties should Novartis fail to comply. *Id.* at 2.

Upon receiving HRSA's violation letter, Novartis immediately challenged the agency

action in the U.S. District Court for the District of Columbia. Novartis's challenge was heard alongside a later case brought by United Therapeutics, which had received a similar violation letter. Following full briefing and argument, the District Court vacated HRSA's violation letter and issued a decision rejecting HRSA's purported requirement that manufacturers recognize an unlimited number of contract pharmacies. *Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021). As the District Court explained, HRSA's enforcement letter rested on the contention that the 340B statute "prohibit[s] drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies"—when the 340B statute does no such thing. *Id.* at *9.

The District Court held that "[t]he statute's plain language, purpose, and structure do not *prohibit* drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies," and HRSA's reasoning to the contrary "rest[s] upon an erroneous reading of Section 340B." *Id.* Although the District Court decided against injunctive relief "at this time," the Court made clear that "any future enforcement action must rest on a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions at issue here." *Id.* Because Novartis's "policies do not violate Section 340B under the positions advanced in the Violation Letters and developed in this litigation," the District Court vacated HRSA's violation letter. *Id.*

The U.S. Court of Appeals for the Third Circuit likewise rejected HHS's interpretation of Section 340B in a parallel lawsuit brought by other drug manufacturers. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023). The unanimous Third Circuit panel held unlawful HHS's "efforts to enforce its interpretation" of Section 340B against drug manufacturers that imposed delivery conditions on sales to covered entities using contract pharmacies. *Id.* at 699.

The Third Circuit held that "Section 340B does not require delivery to an unlimited number of contract pharmacies." *Id.* at 703. It identified multiple "structural clues" that "confirm" this "reading of Section 340B," including that "[n]owhere does Section 340B mention contract pharmacies." *Id.* The Court indicated that this omission was intentional, noting that Congress "expressly contemplate[d] drug makers selling discounted drugs through contract pharmacies" in an adjacent (but non-340B) provision of the same authorizing legislation. *Id.* at 704–705. Indeed, three Third Circuit stated that the argument that manufacturers are required to deliver their 340B drugs to third-party contract pharmacies was "one giant leap from the text." *Id.* at 704. To the contrary, "Congress's use of the singular 'covered entity' in the 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *Id.* Because the "drug makers' restrictions on delivery to contract pharmacies [did] not violate Section 340B," the Third Circuit "enjoin[ed] HHS from enforcing against them its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies." *Id.* at 706. The government did not seek further review of the Third Circuit decision, which is now final.

Following both the District Court's and the Third Circuit's decisions, Novartis announced that it was revising its contract pharmacy policy, effective in May 2023. Verified Compl. ¶37. In keeping with both decisions, Novartis's current policy permits hospital covered entities lacking an in-house pharmacy to select a single contract pharmacy location. *Id.* Novartis ships 340B-discounted units to that contract pharmacy location. Novartis also recognizes any arrangements a

hospital covered entity might have with contract pharmacies that the covered entity fully owns and controls. *Id*. Federal grantee covered entities continue to be exempt.[6]

On May 21, 2024, the D.C. Circuit affirmed the decision of the District Court for the District of Columbia. The D.C. Circuit held that the federal 340B statute's "requirement to 'offer' drugs at a certain 'price' does not prohibit distribution conditions, much less require the offeror to accede to any distribution conditions, much less require the offeror to accede to any distribution terms demanded by the offeree." *Novartis*, Slip Op. at 16. The D.C. Circuit thus found that Novartis's revised policy complies with the plain language of the 340B statute.

C. Maryland Enacts Its Own "340B" Legislation.

States then started stepping into the fray. On May 16, 2024, Maryland enacted H.B. 1056, which states that a 340B manufacturer may not "directly or indirectly deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with or otherwise authorized by a covered entity to receive 340B drugs on behalf of the covered entity." *See* H.B. 1056 (to be codified at Md. Health Occupations Code § 12-6C-09.1(C)(1)); *see also* H.B. 1056, 2024 Leg., Reg. Sess. (Md. 2024), Revised Fiscal and Policy Note at 1.[7] A "340B drug" is defined as a covered outpatient drug that "has been subject to an offer for reduced prices by a 340B manufacturer under [the federal 340B statute]." H.B. 1056 (to be codified at Md. Health Occupations Code § 12-6C-09.1(A)(4)). In plain English: The Maryland statute requires manufacturers like Novartis to provide the 340B discount on any transactions that involve contract pharmacies.

[6] A more detailed description of the policy is available at https://340besp.com/Novartis%20CE%20Letter%20April%203%202023.pdf.
[7] *Available at* https://mgaleg.maryland.gov/2024RS/fnotes/bil_0006/hb1056.pdf.

A violation of H.B. 1056 constitutes an unfair, abusive, or deceptive trade practice under the Maryland Consumer Protection Act (MCPA) subject to specified enforcement actions and penalties therein. *See* H.B. 1056 (to be codified at Md. Health Occupations Code § 12-6C-09.1(D)(1)(I)(1) & Md. Code Ann., Com. Law § 13-301(14)(xlii)). An entity that violates the MCPA is subject to a civil fine of up to $10,000 for each violation and up to $25,000 for each repetition of the same violation. *See* Md. Code Ann., Com. Law §§ 13-410(a)-(b). The law imposes criminal penalties as well: A person who violates the MCPA is guilty of a misdemeanor and subject to a fine of up to $1,000 and/or imprisonment for up to one year. *See* Md. Code Ann., Com. Law § 13-411(a). In addition to those MCPA penalties, H.B. 1056 imposes an additional civil fine of up to $5,000 per violation, *see* H.B. 1056 (to be codified at Md. Health Occupations Code § 12-6C-09.1(D)(2)(I)), providing that "each package of 340B drugs . . . shall constitute a separate violation." *Id.* (to be codified at Md. Health Occupations Code § 12-6C-09.1(D)(4)).[8]

Any alleged non-compliance must be investigated by the Office of the Attorney General's Consumer Protection Division or, as applicable, the Maryland Board of Pharmacy (MBOP). *See id*. (to be codified at Md. Health Occupations Code § 12-6C-09.1(D)(1)(I)(2)); *see also* H.B. 1056, 2024 Leg., Reg. Sess. (Md. 2024), Revised Fiscal and Policy Note at 2, https://mgaleg.maryland.gov/2024RS/fnotes/bil_0006/hb1056.pdf. H.B. 1056 further authorizes, as part of any such investigation, the investigation of an affiliate or a contractor of the 340B manufacturer, including a wholesaler or third-party logistics provider. *See* H.B. 1056 (to be codified at Md. Health Occupations Code § 12-6C-09.1(D)(1)(II)).

[8] A "package of 340B drugs" means "the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product." *See* H.B. 1056, 2024 Leg., Reg. Sess. (Md. 2024), Revised Fiscal and Policy Note at 2, https://mgaleg.maryland.gov/2024RS/fnotes/bil_0006/hb1056.pdf.

ARGUMENT

To secure a preliminary injunction, a movant must establish (1) that it is likely to succeed on the merits, (2) that it is likely to suffer irreparable harm in the absence of preliminary relief, (3) that the balance of equities tips in its favor, and (4) "that an injunction is in the public interest." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also Air Evac EMS, Inc. v. McVey*, 37 F.4th 89, 102–103 (4th Cir. 2022) (applying the four-factor test from *Winter*, and noting that "[t]he requirements for a preliminary injunction are well-settled").

"At this stage, the first factor"—Novartis's likelihood of success on the merits—"is the 'most important' one." *Casa de Maryland, Inc. v. Wolf*, 486 F. Supp. 3d 928, 949 (D. Md. 2020) (quoting *Aamer v. Obama*, 742 F.3d 1023, 1038 (D.C. Cir. 2014)). And as here, where "the government is a party," "the last two factors merge." *Kravitz v. United States Dep't of Com.*, 366 F. Supp. 3d 681, 755 (D. Md. 2019) (quoting *Pursuing Am.'s Greatness v. FEC*, 831 F.3d 500, 511 (D.C. Cir. 2016)). All four factors strongly favor granting the requested relief here.

I. NOVARTIS IS LIKELY TO PREVAIL ON THE MERITS.

A. H.B. 1056 Violates The Supremacy Clause.

1. Maryland's Law Is Preempted By The Federal 340B Statute.

H.B. 1056 is preempted by the federal 340B statute under principles of field preemption and conflict preemption.

a. *Field Preemption*.

The longest-standing preemption principle is the basic one Chief Justice Marshall pronounced more than 200 years ago: "[C]ongress should be able to exercise its constitutional powers, at its own discretion, without being subject to the control of state legislation." *McCulloch v. Maryland*, 17 U.S. 316, 330 (1819). A state statute is subject to field preemption where (1)

Congress's "framework of regulation [is] 'so pervasive' " that Congress has "left no room for the States to supplement it," or (2) where there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). State statutes that diminish federal control over enforcement, and detract from a unified regulatory scheme that Congress has established, are especially likely to violate the Supremacy Clause under field preemption principles.

The 340B Program is just such a unified regulatory scheme, reflecting both a pervasive framework of regulation and predominating federal interests—and Maryland's H.B. 1056 directly interferes with that scheme. The 340B statute implements a "single integrated and all-embracing system"; exactly the type of encompassing federal action that preempts the field. *See, e.g.*, *Hines v. Davidowitz*, 312 U.S. 52, 74 (1941); *American Ins. Ass'n v. Garamendi*, 539 U.S. 396, 419 n.11 (2003). And in crafting the 340B statute, Congress created a comprehensive federal remedial scheme—one that provides its own enforcement pathway and delineated remedies, including a provision for civil penalties. *See* 42 U.S.C. §§ 256b(d)(3)(A)–(B). For that reason, the Supreme Court has held that the federal 340B Program is to be administered—and enforced—solely by or through the federal government.

In *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), county-operated 340B facilities filed a lawsuit against various drug manufacturers, alleging that they were charging prices in excess of those permitted under the manufacturers' PPAs. The plaintiffs' claims were styled as third-party beneficiary claims for breach of contract under state law. The Court rejected the plaintiffs' attempt to manufacture a state law right of action for violations of the federal 340B statute, noting: "Congress placed the Secretary (acting through her designate, HRSA) in control of

§ 340B's drug-price prescriptions. That control could not be maintained were potentially thousands of covered entities permitted to bring suits alleging errors in manufacturers' price calculations." *Id*. at 114.

The Supreme Court's decision was predicated at least in part on the fact that Congress directed HHS to create a comprehensive 340B monitoring and enforcement regime, which included a provision allowing for HRSA enforcement, civil penalties, audits initiated by HRSA and/or the manufacturer, and/or administrative dispute resolution procedures for aggrieved 340B entities in certain narrow circumstances. *See, e.g.*, 42 U.S.C. § 256b(d). The Court noted that "Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements,' and to render the agency's resolution of covered entities' complaints binding, subject to judicial review under the APA." *Astra USA*, 563 U.S. at 121–122 (citing 42 U.S.C. § 256b(d)(3)(C)). The Court noted also that the federal government had filed an amicus brief in support of preemption, explaining that "spreading the enforcement burden" to other entities is "hardly what Congress contemplated when it 'centralized enforcement in the [federal] government.' " *Id.* at 119–120 (also noting the federal government's claim that the state law claims were "at odds with Congress' unitary administrative and enforcement scheme").

In the same manner, H.B. 1056 intrudes on this federally occupied field. By purporting to create a separate, state-specific pathway to enforce 340B requirements, Maryland's statute runs afoul of the Supreme Court's admonition that using state law to enforce federal 340B requirements is "incompatible with the statutory regime." *Astra USA*, 563 U.S. at 113. Congress has left "no room for the States to supplement it[s]" federal regulatory scheme, instead occupying the field

with an exclusive federal enforcement pathway. *See Arizona*, 567 U.S. at 399. And Congress gave HRSA—and HRSA alone—the authority to regulate pricing of 340B drugs. *See Forest Park II v. Hadley*, 336 F.3d 724, 732 (8th Cir. 2003) ("[S]tate statutes may not interfere with the implementation of a federal program by a federal agency."); *PPL EnergyPlus, LLC v. Nazarian*, 753 F.3d 467, 475 (4th Cir. 2014), *aff'd sub nom. Hughes v. Talen Energy Mktg., LLC*, 578 U.S. 150 (2016) (holding state agency's order was field preempted where federal agency had "exclusive power to regulate wholesale sales of energy in interstate commerce").

b. *Conflict Preemption*.

H.B. 1056 also is preempted by the federal 340B statute under principles of conflict preemption. *See City Of Charleston v. A Fisherman's Best, Inc.*, 310 F.3d 155, 169 (4th Cir. 2002). State laws are preempted where they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Conflict preemption is also found when a state law "interferes with the methods by which the federal statute was designed to" achieve those purposes and objectives. *International Paper Co. v. Ouellette*, 479 U.S. 481, 492, 494 (1987).

First, Maryland's H.B. 1056 conflicts with federal 340B law by purporting to unilaterally expand the universe of sales eligible for the 340B discount. As multiple federal courts have found, there is no federal statutory requirement that a drug manufacturer honor unlimited contract pharmacy arrangements. *Sanofi Aventis*, 58 F.4th at 703; *Novartis*, Slip. Op. at 8. The omission of a contract pharmacy requirement reflects a deliberate choice made by Congress: to confer a pricing benefit on a narrow class of covered entities while minimizing the reciprocal burden on manufacturers. That narrow class did not include contract pharmacies. In fact, Congress "expressly contemplate[d] drug makers selling discounted drugs through contract pharmacies" in

an adjacent provision of the legislation relating to another (non-340B) program—but did not do so in the 340B statute. *Sanofi Aventis*, 58 F.4th at 704–705.

Yet H.B. 1056 purports to override that exact Congressional determination and require manufacturers to recognize an unlimited number of contract pharmacies, significantly expanding the number of 340B discounts owed by manufacturers, and upsetting the careful balance struck by Congress, as recognized by other federal courts. *See, e.g.*, *A Fisherman's Best, Inc.*, 310 F.3d at 173 (holding a resolution was preempted where it conflicted with federal agency's regulations and national management of fish and fisheries). It is no cure that Maryland identifies a policy rationale that purportedly parallels the federal government's interest in maintaining the 340B program. H.B. 1056 is preempted even if Maryland purports to have the same overarching goal as the federal government. *See, e.g.*, *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 379–380 (2000) ("conflicting means" of reaching "a common end" are preempted).

Maryland's H.B. 1056 also conflicts with the exclusive enforcement mechanism spelled out in the 340B statute. Congress made its intent plain: The federal 340B Program must be enforced by or through HRSA, with the aim of creating a centralized enforcement process. *Astra USA*, 563 U.S. at 116. H.B. 1056 erects a substantial obstacle to that centralized federal process by creating its own enforcement pathway before state administrative agencies. The Maryland law deputizes the State Attorney General's office and Board of Pharmacy to impose civil penalties under the unfair trade practices statute, adds an additional fine of up to $5,000 per violation, and brands with criminal liability any manufacturer that violates the state law. All of that undermines the remedial scheme created by Congress. *Arizona*, 567 U.S. at 406 (state law that "attempts to achieve one of the same goals as federal law" but "involves a conflict in the method of enforcement . . . 'can be fully as disruptive to the system Congress erected as conflict in overt policy' ") (quoting

Amalgamated Ass'n of St., Elec. Ry. & Motor Coach Emp. of Am. v. Lockridge, 403 U.S. 274, 287 (1971)); *Wisconsin Dep't of Indus., Lab. & Hum. Rels. v. Gould Inc.*, 475 U.S. 282, 286, 288 (1986) (" '[C]onflict is imminent' whenever 'two separate remedies are brought to bear on the same activity.' ") (citation omitted).

Maryland is not alone; other states have begun enacting their own 340B laws as well, including Arkansas, Louisiana, Mississippi, West Virginia, Kansas, and Minnesota. The more of these state laws that pass, the more that Congress's vision of a national, uniform enforcement process is under assault. A patchwork of laws purporting to delegate enforcement powers to individual states may not be used to frustrate that objective. As the Supreme Court noted in *Astra USA*, Congress placed "centralized enforcement in the [federal] government" and created a "unitary administrative and enforcement scheme" precisely so that HHS could "administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Astra USA*, 563 U.S. at 119–120. The "interdependent nature of the two programs' requirements means that an adjudication of rights under one program must proceed with an eye towards any implications for the other." *Id.* at 120 (citation omitted). "With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial." *Id.*; *see also id.* at 120 n.6 ("HHS can use its expertise to ascertain and balance the competing interests.").

In a recent decision, the Eighth Circuit found that an Arkansas 340B law was not preempted by federal 340B law. *Pharmaceutical Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1146 (8th Cir. 2024). That out-of-circuit decision was wrong for a number of reasons—most principally, because it failed to adequately accommodate the Supreme Court's recognition in *Astra USA* of the need for a "unitary administrative and enforcement scheme" for the federal 340B law that operates on a "nationwide basis." *Astra USA*, 563 U.S. at 120.

Because H.B. 1056 flouts the oversight scheme mandated by Congress and seeks to circumvent federal law, it is unenforceable under the Supremacy Clause. *See Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 326 (2016).

2. H.B. 1056 Law Is Preempted By Federal Drug Laws.

The Maryland statute also is preempted by federal drug laws, including those governing regulatory exclusivity and patent protection periods. These laws reflect the outcome of a grand bargain: Brand name manufacturers take on enormous risks and costs in researching and developing new drugs, which are approved based on clinical trials showing that the products are safe and effective. In contrast, generic manufacturers are permitted to utilize the clinical data submitted by brand name manufacturers to establish the safety and effectiveness of their products. *Purepac Pharms. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004). In exchange, brand name manufacturers are given a federally protected, exclusive right to sell their products at market prices for specified periods of time before generic entry. These periods include both regulatory exclusivity periods and patent protection periods. H.B. 1056 unlawfully undermines the incentives driven by both types of exclusivity.

Start with drug regulatory exclusivity periods. Congress directed the Food and Drug Administration (FDA) to recognize various periods of market exclusivity following approval of new drugs, to reward manufacturers for innovation undertaken at considerable risk and expense. *See* 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii) (five years exclusivity for new chemical entities not previously approved by the FDA); *id.* § 355(c)(3)(E)(iii)-(iv), (j)(5)(F)(iii)-(iv) (three years exclusivity to reward additional clinical testing for new indications or to develop new dosages); *id.* § 355a (six months additional exclusivity for pediatric clinical testing); *id.* § 360cc (seven years exclusivity for "orphan drugs" used to treat rare diseases).

These regulatory exclusivity periods were crafted by Congress in order to incentivize brand name manufacturers to engage in research and development in critical areas. For example, manufacturers are awarded a seven year orphan drug exclusivity period when they invest in therapies that serve small patient populations afflicted with rare diseases, where the economic realities would otherwise disincentivize resource investment. *Id.* § 360cc. FDA awards pediatric exclusivity to manufacturers to incentivize testing on critical dosing and labeling information for pediatric patient populations. *Id.* § 355a. Each of these periods is intended to allow manufacturers to sell their products without generic competition for a specified period of time in order to recoup their investment and provide incentives for them to perform the relevant studies.

A similar bargain underlies patent exclusivity periods. Congress has plenary authority under the U.S. Constitution to establish and oversee the patent laws, which provide a system of incentives "[t]o promote the Progress of Science and useful Arts." Art. I, § 8, cl. 8. In 1984, Congress enacted the "Hatch-Waxman" amendments to the FDCA, which among other things created a framework for patent litigation between brand manufacturers and generic manufacturers. Under the resulting patent framework applicable to drug approvals, innovative manufacturers are "impelled to invest in creative effort" on the promise that they will obtain "a federally protected 'exclusive right'" to sell their inventions for a limited period. *Biotechnology Indus. Org. v. District of Columbia,* 496 F.3d 1362, 1371–74 (Fed. Cir. 2007) ("*BIO*").

These patent exclusivity periods are distinctively federal and leave no room for state interference. "Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989); *Southeastern Pennsylvania Transp. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015) ("Federal patent law contemplates the tradeoffs between

exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing Gilead to lower its prices or disgorge profits from the sale of its patented drugs.").

In short, "Congress' regulation of our nation's pharmaceutical industry is grounded in large part in a complex balance of economic forces and regulatory exclusivity designed to encourage and reward the innovation, research, and development of new drugs." *Pharmaceutical Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 65 (D.D.C. 2005), *aff'd sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371–74 (Fed. Cir. 2007). The public reaps the benefit of immediate access to a new product during the innovator manufacturer's exclusivity period, and lower prices once that period ends.

For this reason, state laws seeking to reduce the price of pharmaceutical products during their patent terms have been found to be preempted by federal law. *See Biotechnology Indus. Org.*, 496 F.3d 1362 ("*BIO*"). In *BIO*, the Federal Circuit held that a D.C. law that capped the price of patented pharmaceutical products was preempted by the federal patent law. The Court noted that the "underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make"; a state may not "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1374. The Court thus found the D.C. law preempted: "By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.*

H.B. 1056 is unlawful for similar reasons. Maryland's law places a ceiling (and, here, an extremely low one) on the prices at which Novartis may sell drugs in transactions involving contract pharmacies—even *during* federally guaranteed exclusivity periods. H.B. 1056 thus

artificially reduces drug prices on a broad set of transactions not contemplated by federal 340B law, reducing the incentives Congress provided for brand name manufacturers to invest in new therapies. And by purporting to expand the number of transactions in which manufacturers must provide steep discounts on the prices they may charge for their drug products—even while those drugs are still subject to federal exclusivity periods—the state law interferes with the incentive structure created by the federal drug laws. In doing so, H.B. 1056 interferes with the delicate balance Congress struck to incentivize critical drug research.

B. H.B. 1056 Violates The Dormant Commerce Clause.

Maryland's law also violates the dormant Commerce Clause. Under the Commerce Clause, Congress has the power to regulate commerce among the several states. U.S. CONST. art. I, § 8, cl. 3. Although the clause is framed in terms of an affirmative grant to Congress, courts also recognize a "dormant" aspect of the Commerce Clause. This dormant aspect "prevents the States from adopting protectionist measures and thus preserves a national market for goods and services." *Tennessee Wine & Spirits Retailers Ass'n v. Thomas*, 588 U.S. 504, 514 (2019).

H.B. 1056 violates the dormant Commerce Clause in numerous ways.

1. H.B. 1056 Is Unlawfully Extraterritorial

First, the Maryland law violates the dormant Commerce Clause because it purports to regulate conduct that takes place wholly outside of Maryland.

In *Association for Accessible Medicines v. Frosh*, 887 F.3d 664, 674 (4th Cir. 2018), the Fourth Circuit held that a Maryland law prohibiting a manufacturer or wholesaler from engaging in "price gouging" in the sale of prescription drugs violated the dormant Commerce Clause. The Court noted that the Maryland "price gouging" law (like the Maryland 340B law at issue here) targeted *manufacturers and wholesalers*, both of which were largely located out of state—not the retailers that ultimately sold the drugs to patients in Maryland. "The Act, by its own terms, is not

fixated on the price the Maryland consumer ultimately pays for the drug. Instead, the lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*." *Id*. at 671 (emphasis in original). The Court held that, by focusing on manufacturers and wholesalers, the Maryland law targeted up-stream transactions occurring out of state. *Id.* at 672 (noting that "the Act is effectively a price control statute that instructs manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland").

Similarly, in *Pharmaceutical Research & Manufacturers of America v. District of Columbia*, 406 F. Supp. 2d 56, 70 (D.D.C. 2005) ("*PhRMA*")—the district court decision that led to the *BIO* Federal Circuit decision described above[9]—the District Court for the District of Columbia invalidated a state drug pricing law on dormant Commerce Clause grounds. The law prohibited manufacturers from a selling drug that "results in the prescription drug being sold in the District for an excessive price." *Id.* at 68. The district court noted that "Plaintiffs' members manufacture patented prescription drugs wholly outside the District of Columbia and are neither headquartered in the District, nor operate warehouses in the District. Thus, in practice, plaintiffs' members sell 'the overwhelming bulk' of their patented prescription drugs in out-of-state transactions to wholesalers or large retail chains that maintain their own warehousing and retail distribution system." *Id*. The court therefore found that a state drug pricing law "effect[ed] an impermissible extraterritorial reach" and violated the dormant Commerce Clause. *Id.* at 70.

Like the manufacturers in *Frosh* and *PhRMA*, Novartis is not located in Maryland. Novartis typically sells its products to national wholesalers and distributors located around the country. Verified Compl. ¶ 29. In turn, the wholesalers sell the products to national pharmacy

[9] On appeal, the Federal Circuit addressed only the preemption argument.

chains, whose headquarters are also typically located outside the state. *Id.* Further down the notoriously complicated drug distribution chain, the drug products at issue make their way to a pharmacy located in Maryland, where they are dispensed to patients. *Id.* A covered entity wishing to claim a 340B discount typically does not request or receive the discount directly from Novartis. Instead, covered entities buy from (largely out-of-state) wholesalers and retailers, and obtain the 340B discount from them. *Id.* The national wholesalers then separately submit a chargeback to manufacturers in a transaction that typically takes place between two out-of-state entities. *Id*.

Like the state laws at issue in *Frosh* and *PhRMA*, H.B. 1056 targets a transaction that occurs between drug manufacturers and wholesalers. Md. Health Occupations Code § 12-6C-09.1. In fact, the original text also covered "wholesale drug distributor[s]," but that language was stricken from the bill. Thus, the conduct that the state law "targets is the upstream pricing and sale of prescription drugs"—which by definition typically takes place outside of the state. That is unconstitutional. *Frosh*, 887 F.3d at 671–672.

While the Supreme Court recently tightened the requirement for showing discrimination in dormant Commerce Clause cases, it did not disturb the longstanding constitutional bar on laws "*directly* regulat[ing] out-of-state transactions by those with *no* connection to the State." *National Pork Producers Council v. Ross*, 598 U.S. 356, 376 n.1 (2023) (emphasis in original). To the contrary, the state law at issue in *Pork Producers* barred the *in-state* sale of pork products derived from breeding pigs confined to small pens. The state law attached to the *pigs*, not to the out-of-state pig farmers. And it was not a price regulation statute; the law regulated safety conditions that the industry argued would necessarily have an impact on prices both in and out of state. Lest there be any doubt on the status of this line of cases after the Supreme Court's decision in *Pork Producers*, the Supreme Court itself favorably cited *Frosh*. *Id.* at 374.

For that reason, lower courts have held that *Pork Producers* did not change the Court's longstanding jurisprudence addressing state laws that seek to regulate conduct taking place wholly outside the state. *See, e.g., Association for Accessible Medicines v. Ellison*, No. 23-CV-2024 (PJS/JFD), 2023 WL 8374586, at *2, 3–4 (D. Minn. Dec. 4, 2023) (state law likely violates dormant Commerce Clause because "it directly regulates transactions that take place wholly outside of" the state and finding no "support for the notion that the dormant Commerce Clause permits Minnesota to directly regulate a sale that occurs in another state simply because the product eventually makes its way into Minnesota"); *National Shooting Sports Found. v. Bonta*, No. 23-CV-0945-AGS-KSC, 2024 WL 710892, at *7 (S.D. Cal. Feb. 21, 2024) (state rule likely violates dormant Commerce Clause because it "reaches beyond California's borders and directly regulates out-of-state commercial transactions").

Regardless, even if *Pork Producers* could be read to require proof of discrimination to bolster an extraterritoriality claim, H.B. 1056 *is* discriminatory, for the reasons spelled out below.

2. H.B. 1056 Has Both A Discriminatory Intent And Effect

The Supreme Court emphasized in *Pork Producers* that at the "very core" of the dormant Commerce Clause is a simple "antidiscrimination principle": No matter how earnestly a state wishes to enact "regulatory measures designed to benefit in-state economic interests," its legislation cannot advance the sort of "economic protectionism" that privileges its homegrown commercial interests while "burdening out-of-state competitors." *National Pork Producers Council*, 598 U.S. at 377. A law that discriminates against out-of-state economic entities will be struck down unless the state demonstrates that the law is "narrowly tailored to advance a legitimate local purpose" and that there is no nondiscriminatory alternative. *Tennessee Wine & Spirits Retailers Ass'n*, 588 U.S. at 518, 540.

H.B. 1056 violates this core principle: It privileges *in-state* economic interests of hospitals and pharmacies at the expense of *out-of-state* manufacturers like Novartis. A law that discriminates against interstate commerce is *per se* invalid and "will survive strict scrutiny only if it advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives." *Colon Health Centers of Am., LLC v. Hazel*, 813 F.3d 145, 152 (4th Cir. 2016) (citation omitted) (similar).

In this context, discrimination means "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter." *Oregon Waste Sys., Inc. v. Department of Env't Quality of State of Or.*, 511 U.S. 93, 99 (1994); *Fulton Corp. v. Faulkner*, 516 U.S. 325, 330 (1996). The Supreme Court has advised courts to conduct a "case-by-case analysis" to determine whether a state law discriminates. *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 201 (1994). The focus "must be the practical operation of the statute, since the validity of state laws must be judged chiefly in terms of their probable effects." *Colon Health Centers*, 813 F.3d at 152 (citation omitted). A state law may discriminate against interstate commerce on its face, in its practical effect, or in its purpose. *Id.* at 154.

H.B. 1056 has a discriminatory intent: The purpose of the law is to protect in-state hospitals and pharmacies, at the expense of out-of-state manufacturers. H.B. 1056 also has a discriminatory effect: Out-of-state manufacturers are compelled to provide their products at 340B-discounted prices to Maryland-based hospitals and pharmacies. That privileges in-state industries while significantly burdening out-of-state manufacturers like Novartis. Because Maryland's law advantages in-state interests at the expense of out-of-state interests, it violates the dormant Commerce Clause. *Pork Producers*, 598 U.S. at 370.

Pork Producers did not overrule longstanding case law striking down price limits that have a discriminatory intent and effect. The Court favorably cited *Baldwin*, which addressed an old New York law that "barred out-of-state dairy farmers from selling their milk in the State 'unless the price paid to' them matched the minimum price New York law guaranteed in-state producers." *Pork Producers*, 598 U.S. at 371–372 (quoting *Baldwin v. GAF Seelig, Inc.*, 294 U.S. 511, 519 (1935)). The Court found that it " 'plainly discriminate[d]' against out-of-staters by 'erecting an economic barrier protecting a major local industry against competition from without the State.' " *Id.* at 372 (citation omitted).

H.B. 1056 is equally protectionist. Out-of-state manufacturers like Novartis are required to give large discounts in Maryland in order to advantage local hospitals and pharmacies. That plainly discriminates against out-of-state manufacturers to protect major local industries. *See Pork Producers*, 598 U.S. at 372. And there are other means to accomplish the purpose of H.B. 1056. For example, Maryland could simply give a direct grant to in-state hospitals or pharmacies. What it cannot do is enact legislation that takes money from an out-of-state private party and hands it to an in-state private party, with both the stated intent and blatant effect of protecting local interests at the expense of out-of-state industries.

3. H.B. 1056 Excessively Burdens Interstate Commerce.

Finally, Maryland's law falters under the balancing test the Supreme Court announced in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); *Pork Producers*, 598 U.S. at 403 (Kavanaugh, J., concurring) ("six Justices of this Court affirmatively retain the longstanding *Pike* balancing test"); *Truesdell v. Friedlander*, 80 F.4th 762, 768 (6th Cir. 2023) (explaining post-*Pork Producers* that, even if a law does not discriminate, a court must ask "whether it nevertheless inflicts a 'substantial harm' on interstate commerce" under *Pike*); *Restaurant L. Ctr., v. City of*

New York, 90 F.4th 101, 118 (2d Cir. 2024) (same). A law will be invalidated if the burdens imposed on interstate commerce are "clearly excessive in relation to the putative local benefits." *Pike*, 397 U.S. at 142.

The burdens that Maryland's law imposes on interstate commerce are clearly excessive in relation to its putative local benefits. *See id.* H.B. 1056 uniquely tilts the bargaining power in favor of in-state pharmacies at the expense of out-of-state drug manufacturers. Novartis is already facing financial burdens in trying to comply with the Maryland law and anticipates losing millions of dollars per year from Maryland's price-setting. Decl. ¶¶ 12. Those burdens will only compound as more states follow suit. A race to the bottom is taking shape already: Arkansas, Louisiana, West Virginia, Mississippi, Kansas, and Minnesota have recently adopted comparable statutes. *See* Ark. Code Ann. § 23-92-601 *et seq.*; La. Rev. Stat. §§ 40:2881–2886. The laws are not identical. Novartis thus must contend with a patchwork of laws purporting to carve out individual states from the federal 340B system, each purporting to make its respective state an island unto itself. *See Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) ("[T]he practical effect of the statute must be evaluated" by considering "how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation."). As other states enact their own variations on Maryland's law, the burden on interstate commerce is monumental; state-specific interests are elevated in precisely the way the dormant Commerce Clause prohibits. *See, e.g.*, *Frosh*, 887 F.3d at 670 (finding a state statute violated the dormant Commerce Clause, in part, where the statute, "if similarly enacted by other states, would impose a significant burden on interstate commerce involving prescription drugs").

Maryland has no valid justification for excessively burdening interstate commerce. *See United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 339 (2007); *Pike*, 397 U.S. at 142. The law lines the pockets of private commercial actors, and does not serve the state's public interest: Most critically, the state law does not require discounts to be passed on to Maryland patients, making for-profit entities the real beneficiaries of what has become a regulatory boondoggle.[10] These discounts generally are not passed on to the patient, but to for-profit entities including pharmacies and administrators. *Novartis*, Slip. Op. at 8.

Even if Maryland could identify a legitimate local purpose, there are other means for advancing its purported purpose that would have "a lesser impact on interstate activities." *Pike*, 397 U.S. at 90. For example, the state could give grants directly to the hospitals and pharmacies that it wishes to advantage. The path that Maryland chose instead—a forced transfer of that funding from an out-of-state actor—is not constitutional.

II. NOVARTIS WILL SUFFER IRREPARABLE HARM ABSENT A PRELIMINARY INJUNCTION.

Absent immediate judicial intervention, Novartis will suffer irreparable harm on several fronts. If H.B. 1056 is not enjoined, Novartis will be exposed to an unconstitutional state enforcement action. A regulated entity may be irreparably injured in the face of threatened enforcement of a preempted law. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992).

Maryland's law also threatens to impose significant financial penalties upon Novartis if it does not capitulate to Maryland's law. Any violation by a manufacturer constitutes an unfair, abusive, or deceptive trade practice under the MCPA, *see* H.B. 1056 (to be codified at Md. Health

[10] *See, e.g.*, Peter J. Pitts & Robert Popovian, *340B and the Warped Rhetoric of Healthcare Compassion*, (FDLI Fall 2022) *available at* https://www.fdli.org/2022/09/340b-and-the-warped-rhetoric-of-healthcare-compassion/ (noting that the average profit margin of contract pharmacies on commonly dispensed 340B drugs reaching "an astounding 72%, compared to 22% for non-340B drugs").

Occupations Code § 12-6C-09.1(D)(1)(I)(1) & Md. Code Ann., Com. Law § 13-301(14)(xlii)), and subjects a violating entity to a civil fine of up to $10,000 for each violation and up to $25,000 for each repetition of the same violation. Md. Code Ann., Com. Law §§ 13-410(a)-(b). In addition to those MCPA penalties, H.B. 1056 imposes a civil fine of up to $5,000 per violation, *see* § 12-6C-09.1(D)(2)(I)), and provides that "each package of 340B drugs . . . shall constitute a separate violation." § 12-6C-09.1(D)(4)). A "package of 340B drugs" means "the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser."[11] This is a severe financial remedy.

These financial losses drain Novartis's ability to commit to the same level of investment in the research and development programs that make possible life-saving and life-sustaining uses for its new and existing drug products. Decl. ¶ 10. As a manufacturer of branded products, Novartis relies on the revenues generated from the sales of its drugs to recoup the high costs of developing those drugs. Decl. ¶ 9. H.B. 1056 will require Novartis to transfer its pharmaceutical products at steeply discounted prices *before* its patent protections and the various federal exclusivity periods have run, thereby reducing the incentives crafted by Congress. Those lost opportunities are not recoverable after-the-fact. *CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc.*, 893 F. Supp. 508, 524 (D. Md. 1995) ("Irreparable harm has been found where a patentee's market representation and goodwill would not be fully compensable with money damages.").

The financial losses that are looming for Novartis are not remediable, either. Once the 340B discounts are made, there is no readily apparent mechanism for Novartis to recover them

[11] *See* H.B. 1056, 2024 Leg., Reg. Sess. (Md. 2024), Revised Fiscal and Policy Note at 2, *available at* https://mgaleg.maryland.gov/2024RS/fnotes/bil_0006/hb1056.pdf.

from the contract pharmacies or covered entities—under either federal or state law. HRSA has recently opined that the ADR process only permits manufacturer claims seeking to address duplicate discounts and drug diversion (and even then, only after an expensive and time-consuming audit). 42 U.S.C. § 256b(d)(3)(A); *see also* 89 Fed. Reg. 28,643, at 28,645 (clarifying the "ADR process should be reserved for those disputes set forth in the statutory ADR provision"). The ADR process thus provides no obvious path for Novartis to recoup a 340B discount provided on account of a state law mandate later found to be invalid. And the Maryland's law provides for no such mechanism either. Because Novartis cannot later be made whole for the losses it is about to suffer, injunctive relief is warranted. *See Friendship Edison Pub. Charter Sch. Collegiate Campus v. Nesbitt*, 704 F. Supp. 2d 50, 52 (D.D.C. 2010) (harm can be irreparable in the context of economic harm where such harm "would threaten the existence of its business" or the moneys lost "would be unrecoverable") (citing *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)).

Injury flowing from threatened enforcement takes on a special dimension where, as here, the challenged law imposes *criminal* liability on those who violate it. Through the MCPA, Maryland's imposes a criminal penalty of up to $1,000 per violation and/or imprisonment for up to one year. *See* Md. Code Ann., Com. Law § 13-411(a). There are significant reputational harms flowing from criminal and civil liability as well: If Maryland finds that Novartis violated the law, that decree will stigmatize Novartis and label it a wrongdoer. Novartis faces risk of irremediable harm if it is held liable for violating a state law, even if the law is later found to be invalid.

Manufacturers like Novartis thus face a Hobson's choice: risk draconian penalties, or comply with an unconstitutional law. Either pathway causes irreparable harm. The harm occasioned by forced compliance with an invalid law is irreparable. *See, e.g.*, *BST Holdings, L.L.C.*

v. Occupational Safety & Health Admin., United States Dep't of Lab., 17 F.4th 604, 618 (5th Cir. 2021) ("[C]omplying with a regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs." (citations omitted; emphasis in original)). The loss of constitutional freedoms constitutes irreparable harm for preliminary-injunction purposes. *Mills v. D.C.*, 571 F.3d 1304, 1312 (D.C. Cir. 2009) ("It has long been established that the loss of constitutional freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.") (internal quotation marks and citation omitted); *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (same); *United Church of the Med. Ctr. v. Med. Ctr. Comm'n*, 689 F.2d 693, 701 (7th Cir. 1982) (finding irreparable harm where "a given piece of property is considered to be unique" and its loss by "an unconstitutional procedure" cannot be cured by the "[s]ubstitution of another"); Charles Alan Wright et al., 11A Fed. Prac. & Proc. Civ. § 2948.1 (3d ed. 2023) ("When an alleged deprivation of a constitutional right is involved . . . , most courts hold that no further showing of irreparable injury is necessary."). Here, Novartis's constitutional injuries are "certain and great" and there is a "clear and present" need for equitable relief given the risks to Novartis of state enforcement. *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006).

III. THE BALANCE OF EQUITIES FAVORS GRANTING AN INJUNCTION.

The balance of equities tips sharply in favor of the requested relief. "[T]he balance of the equities favors preliminary relief" when the "issuance of a preliminary injunction . . . prevents the state from enforcing restrictions" that are likely to be held invalid. *Leaders of a Beautiful Struggle v. Baltimore Police Dep't*, 2 F.4th 330, 346 (4th Cir. 2021). If "anything, the system is improved by such an injunction." *Id.* There is "no legitimate interest in the operation" of invalid government action. *Association of Am. Publishers, Inc. v. Frosh*, 586 F. Supp. 3d 379, 397 (D. Md. 2022).

There is no irreparable harm on the other side of the ledger: A preliminary injunction that preserves the status quo harms no one. Granting injunctive relief here would not harm Defendants,

as it is well-established that states maintain no interest in enforcing a statute that violates federal law. Indeed, that is "the primary purpose of" temporary injunctive relief: to "preserve the object of the controversy in its then existing condition—to preserve the status quo." *Aamer*, 742 F.3d at 1043 (quoting *Doeskin Prod., Inc. v. United Paper Co.*, 195 F.2d 356, 358 (7th Cir. 1952)). Unlike manufacturers, covered entities can seek chargebacks for discounts retroactively. They therefore suffer no harm if they are temporarily denied the ability to do so while this lawsuit plays out.

Patients also would not be harmed by an injunction. Patients do not receive 340B discounts; the financial benefit accrues to covered entities and their contract pharmacies, and there is no federal or state requirement that the savings be spent on patient-specific pursuits. Nor would patients be denied access to any drugs. To the contrary, the contract pharmacy transaction is typically not identified as purportedly triggering a 340B discount until long after the patient has filled his or her prescription and paid any cost-sharing. Patients generally do not gain any benefit from the 340B discount and therefore would not be harmed if the Court were to grant Novartis's requested injunction.

IV. GRANTING AN INJUNCTION WOULD PROTECT THE PUBLIC INTEREST.

Finally, an injunction here would serve the public interest. The public has a substantial interest in seeing that federal law is enforced and not countenancing state efforts to reset the metes and bounds of participation in federal healthcare programs. *Roe v. Department of Def.*, 947 F.3d 207, 230–231 (4th Cir. 2020) (the "public undoubtedly has an interest in seeing its governmental institutions follow the law"); *Fund for Animals, Inc. v. Espy*, 814 F. Supp. 142, 152 (D.D.C. 1993) ("there is a strong public interest in meticulous compliance with the law by public officials"); *see also, e.g.*, *O'Donnell Const. Co. v. D.C.*, 963 F.2d 420, 429 (D.C. Cir. 1992); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (district court properly concluded public interest

in "faithful application of the laws" favored granting preliminary relief); *League of Women Voters of the United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (there is "a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations"). That includes ensuring state governments comply with federal law.

CONCLUSION

For the foregoing reasons, Novartis's motion for a preliminary injunction should be granted.

Respectfully submitted,

/s/ Susan M. Cook
Catherine E. Stetson*
Susan M. Cook (D. Md. Bar No. 21636)
Karl A. Racine**
Marlan Golden*
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, DC 20004
Tel: (202) 637-5600
cate.stetson@hoganlovells.com
susan.cook@hoganlovells.com

**Pro Hac Vice Motion Forthcoming*
***Application for Admission Forthcoming*

Attorneys for Novartis Pharmaceuticals Corporation

Dated: May 29, 2024

CERTIFICATE OF SERVICE

I hereby certify that on May 29, 2024, I electronically filed this memorandum with the Clerk of Court for the United States District Court for Maryland using CM/ECF. This memorandum will be served by process server on the following:

Anthony G. Brown
Maryland Attorney General
200 St. Paul Place
Baltimore, MD 21202
(410) 576-6300

Kristopher Rusinko
Board President
Maryland Board of Pharmacy
4201 Patterson Ave.
Baltimore, MD 21215

/s/ Susan M. Cook
Susan M. Cook

Dated: May 29, 2024